

REMARKS

Reconsideration of this application is respectfully requested. Claim 13 has been amended without prejudice or disclaimer to remove reference to A β aggregation.

No new matter has been added. Claims 13 and 18 are pending and at issue.

Enablement Rejection

Claims 13 and 18 remain rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. According to the Examiner, the specification enables the treatment of A β aggregation in the CNS, but it does not enable protection of all neurons in the CNS (*see* Office action, page 4). The Examiner contends that the working examples demonstrate that donepezil decreases the amount of A β aggregation in cholinergic neurons, but there are no working examples that support completely preventing disorders in all neurons (Office action, pages 4-5). The Examiner concludes that undue experimentation would be required to practice the entire scope of the claimed invention, which includes completely preventing A β toxicity.

According to the specification, “protection” of neurons is defined as providing a “protective effect upon neurons of the central nervous system against various loads resulted from ischemia-like effect” (*see* published specification at ¶155). As pointed out by the Examiner, protection of neurons is also defined as “not only to actually prevent the death of neurons of the central nervous system caused by loads on them (e.g., physical or chemical disorders undesirable for the maintenance of homeostasis, such as stress, trophopathy, diseases, injuries, decreased strength due to surgical operations or the like, prostration, aging; or cytotoxicity), but also to prevent the lowering of functions of neurons” (*see* specification at ¶156).

Applicants submit that the Examiner improperly construes the claims based on an unduly broad definition of “protection.” The Examiner states that “total inhibition” of toxicity induced by A β is not enabled. However, as noted above, the definition of “protection” in the specification only calls for preventing “cell death” and the “lowering of neuronal function.” Therefore, “protection” does not mean “completely preventing [all] disorders” as alleged by the

Examiner. Therefore, the working examples enable the claimed subject matter in view of this definition of “protection.”

Anticipation Rejection

Claims 13 and 18 remain rejected under 35 U.S.C. § 102(b) as anticipated by Emilien, et al., *Arch. Neurol.*, 57:454-459 (2000), as evidenced by Michaelis, *JPET*, 304:897-904 (2003). The Examiner maintains that Emilien teaches that donepezil is an FDA-approved acetylcholinesterase [inhibitor] approved for treating Alzheimer’s disease (AD). The Examiner again takes the position that treatment of neuron disorders induced by A β toxicity is inherently taught by Emilien, and that Michaelis teaches that A β plaques and A β toxicity are associated with AD. Thus, the Examiner concludes that donepezil would necessarily treat A β toxicity because it is known to treat AD and has been used previously in AD populations (*see* Office Action, pages 6-7).

Claim 13 has been amended, without prejudice or disclaimer, to call for a method of protecting neurons of the central nervous system, comprising administering an effective amount of the recited compound to protect neurons of a patient in need thereof from damage induced by cerebral ischemia, excitotoxicity, or A β toxicity (*see* amended claim 13).

Emilien does not disclose or suggest a method of protecting neurons from ischemia, excitotoxicity, or A β toxicity by administering the claimed compound. Emilien is merely a review article describing various approved, and not yet approved drugs relevant for treating Alzheimer’s disease (as of 2000). Emilien describes donepezil as a piperidine-based AChE (acetylcholinesterase) inhibitor with specificity for AChE. Emilien is silent with regard to whether donepezil would necessarily protect neurons of a patient in need thereof from damage induced by A β toxicity.

Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. *See* MPEP § 2131 (8th Ed., Rev. 4, Jan. 2006). “A claim is anticipated only if each and every element as set forth in the claim is found, either

expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Emilien provides no teachings regarding a method of protecting neurons of the central nervous system, comprising administering an effective amount of the recited compound to protect neurons of a patient in need thereof from damage induced by cerebral ischemia, excitotoxicity, or A β toxicity.

In view of the remarks provided herein, Emilien fails to anticipate claims 13 and 18.

CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner’s Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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